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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,016	02/04/2002	Bernhard H. Van Lengerich	5352USA	7141

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EXAMINER
PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,016	VAN LENGERICH ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9,11-15,17-23 and 25-29 is/are rejected.

7)☒ Claim(s) 10, 16 and 24 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-29 are presented for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 13-15, 20 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhatty (J. Cereal Sci. 22:163-170 (1995)).

Bhatty describes processes of preparing β-glucan from barley and oats, to yield a dry powder. See, e.g., page 164, Fig. 1. Note specifically that the described processes uses ground, i.e. "comminuted," barley or oat bran as the starting material. See first paragraph, left column, page 164. Note also that applicant's process is not recited using language requiring the steps to be performed in any particular order.

The first step of Bhatty's processes is a step of forming an aqueous slurry of the comminuted material in NaOH, the same first step as in the cited claims. Bhatty also contains two

acidification steps, one is a pH adjustment to pH 6.5 with HCl, and the other is a later adjustment to pH 4.5 with HCl. Bhatty's second pH adjustment clearly anticipates applicant's claimed adjustment to "about 4.2". Thus, Bhatty discloses the first two of the claimed steps.

Bhatty further describes the addition of Termamyl (i.e., α-amylase) to the aqueous solution, thereby describing the third step in applicant's claimed process, the addition of an enzyme capable of hydrolyzing at least a portion of the soluble components.

Bhatty also describes two centrifugation steps in both the lab and pilot plant protocols (second and fifth step in each protocol), which removes insoluble materials. Thus, Bhatty discloses the claimed steps of separating water insoluble materials from the aqueous solution.

Bhatty also describes at least two heating steps in the pilot plant protocol (the heating for the enzymatic digestion, as well as the heating required to maintain at 50 degrees C for the acidification to pH 4.5. The laboratory protocol contains only the heating for the enzymatic digestion. Thus, Bhatty describes applicant's heating step.

Lastly, Bhatty describes that the preparation can be freeze-dried to a powder, thereby disclosing applicant's water

removal step. In sum, because Bhatty discloses a process comprising all of the claimed steps, a holding of anticipation is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11-15, 17-23 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatty (J. Cereal Sci. 22:163-170 (1995)) in view of Kanauchi et al (Cereal Chem. 87(2):121-124 (2001)) and Bamforth et al (J. Inst. Brew. 107(4):235-240 (2001)).

As discussed above, Bhatty describes processes of preparing β-glucan from barley and oats, to yield a dry powder. Bhatty differs from the cited claims in failing to disclose the use of the claimed cellulase, hemicellulase, xylanase and pentosanase enzymes recited in the claims. However, each of Kanauchi and Bamforth discloses that the claimed enzymes improve the purification of glucan from the starting materials. See Kanauchi, e.g., in abstract ("[v]arious purified enzymes promote the solubilization of glucan from denatured and dehusked barley."). See also Bamforth, at abstract ("[t]he release of glucan is greatly enhanced if exogenous enzymes are added.") Thus, the artisan of ordinary skill at the time of applicant's invention practicing Bhatty's glucan purification process clearly would have been motivated by the Kanauchi/Bamforth disclosure of the advantages of exogenous enzyme addition to have added the enzymes of Kanauchi/Bamforth to the Bhatty process. A holding of obviousness over the cited process claims is therefore required. Moreover, in view of the fact that adding such enzymes would have yielded a product as recited in the product claims, those claims must also be held obvious.

Lastly, although none of the cited references discloses the precise amounts of material recited in applicant's claims 2, 3 and 12, the artisan of ordinary skill clearly would have

recognized the concentration of starting material to be a result-effective parameter, based on the knowledge that a different starting concentration of grain material would have been expected to affect process parameters, including the ultimate result of the process. Thus, because the determination of suitable concentrations of starting material in Bhatty's process would have been a matter of routine optimization on the part of the artisan of ordinary skill, those claims reciting those concentrations must be considered obvious under § 103(a).

Claim Rejections - 35 USC § 102/103

Claims 17-19 and 25-29 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Bhatty (J. Cereal Sci. 22:163-170 (1995)).

The reference discloses a product which appears to be identical to the presently claimed product, based on the fact that the prior art product is the identical compound, β-glucan, produced from the identical starting material, barley or oat grain, using the same basic series of steps as recited in the claims. Consequently, the claimed product appears to be anticipated by the reference.

However, even if the reference product and the claimed product are not one and the same and there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that any nominal difference between the claimed and prior art product would be the normal difference expected to occur between batches of material prepared from a starting material, cereal grain, which would itself have been expected to vary depending on growth conditions, etc. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Regarding the propriety of this type of alternative rejection, note that MPEP § 2113 states that:

> . . . [w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972).

MPEP § 2113 also clearly states that

'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for

> product-by-process claims because of their peculiar nature' than when a product is claimed in the conventional fashion. *In re Fessmann*, 180 USPQ 324 (CCPA 1974)."

Conclusion

No claims are allowed. However, claims 10, 16 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Specifically, although the yeast fermentation of materials from cereal is well known in the art, no prior art suggests combining disclosures of such fermentations with a process such as Bhatty's.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the

organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP